

AMENDMENTS TO THE DRAWINGS

The attached drawing sheets include changes to Figure 7 to move the label for part C from the bottom of the first page of Figure 7 to the top of the second page of Figure 7. The attached drawing sheets also include changes to label the top graph of Figure 11 as part A and the bottom graph of Figure 11 as part B.

Attachment: Replacement Figures 7 and 11

REMARKS**I. Status of Claims**

Claims 1 and 92-98 are pending. Claims 2-91 were previously canceled.

II. Information Disclosure Statements

The Examiner has pointed out duplicate entries on the Information Disclosure Statement filed February 1, 2008 and incorrectly listed issue dates for U.S. Patent Nos. 5,455,170 and 5,445,940 in the Information Disclosure Statement filed July 22, 2005. Applicants thank the Examiner for pointing out these issues and for citing U.S. Patent Nos. 5,455,170 and 5,445,940 on PTO-892.

III. Objections to the Drawings

The drawings have been objected to for the letters in Figure 2 not being explained in the specification. To address this objection, the Applicants have amended paragraph [0051] in the specification to include an explanation of all parts of Figure 2. Support for this amendment can be found, for example, in paragraph [0398] of the specification.

The drawings have been further objected to for Figure 7C appearing on two separate sheets. To address this objection, the Applicants have submitted replacement sheets with Figure 7 amended so that the label for part C is correctly placed directly above the figure for part C on the second sheet of the drawing.

The drawings have been further objected to for Figures 9 A-D not being separately discussed in the Brief Description of Drawings. To address this objection, the Applicants have amended paragraphs [0064], [0065], [0066], and [0067] in the specification to clearly label the description of each part of Figure 9.

Finally, the drawings have been objected to for the parts of Figure 11 not being labeled as A-D. To address this objection, the Applicants have submitted a replacement sheet with Figure 11 amended so that the top graph of the figure is labeled as A and the bottom half of the figure is labeled as B. Figure 11 only contains 2 parts. Further, the Applicants have amended paragraph [0070] of the specification so that parts A and B of Figure 11 are clearly labeled in the Brief Description of Drawings.

IV. Rejection under 35 U.S.C. § 102(e)

Claim 1 is rejected under 35 U.S.C. 102(e) as being allegedly clearly anticipated by Moore et al (U.S. Patent Application Publication 2001/0021700). Specifically, the Office asserts that Moore et al teaches the diagnosis and treatment of disorders of the immune system by monitoring the expression of a gene involved in hematopoiesis.

Applicants respectfully traverse the rejection and its supporting remarks. In order to anticipate a claim, a single reference must teach every limitation of the claim. Claim 1 is directed to a method of assessing the immune status of an individual by detecting the expression level of genes which are expressed at different levels depending on the rate of hematopoiesis or on the distribution of hematopoietic cells along their maturation pathway. Moore et al does not teach each and every limitation of the claim.

First, Moore et al does not teach the claim limitation of a method of assessing the immune status of an individual. Instead, Moore et al teaches the diagnosis and treatment of a variety of immune disorders (paragraph [0198]). An assessment of status is different from diagnosis and treatment of immune disorders. An assessment of immune status involves evaluating the general health status of an individual. Further, an assessment of immune status includes determining appropriate therapies based on general health status as well as monitoring treatment regimens (paragraphs [0131]-[0132]). For example, an assessment of immune status includes the monitoring of chemotherapeutic agents in a cancer patient (paragraph [0136]). In contrast, diagnosis and treatment of immune disorders is a directed activity to a specific disease of the

immune system. As described by Moore et al in paragraph [0655], treatment of an immune system disorder involves the administration of polynucleotides or polypeptides, or agonists or antagonists of the present invention directed to a specific therapeutic target. Thus, assessing the immune status of an individual is different than diagnosis and treatment of an immune system disorder.

Second, Moore et al does not teach the claim limitation of genes that are expressed at different levels depending on the rate of hematopoiesis or on the distribution of hematopoietic cells along their maturation pathway. Instead, Moore et al teaches a *gene expressed primarily in ...immune cells (activated neutrophils, activated T-cells, neutrophils, and dendritic cells)* (paragraph [0195]). This gene expression pattern is different from that taught in the claimed invention. The gene that Moore et al discloses is expressed in activated neutrophils, activated T-cells, neutrophils, and dendritic cells, which are all mature cells of specific hematopoietic lineages. The claim limitation, genes that are expressed at different levels depending on the rate of hematopoiesis or on the distribution of hematopoietic cells along their maturation pathway are expressed dynamically in immature cells compared with mature cells. This dynamic expression pattern in which gene expression levels change depending on the maturation state of the particular hematopoietic cell is in contrast to the static expression of a gene only in mature hematopoietic cells described in Moore et al.

For example, the instant specification demonstrates that it is especially useful to measure gene expression in erythrocytes and platelets because in these lineages some RNAs are specific to the immature forms of these cells (paragraph [0127]). These cells lack a nucleus in their mature form, and RNA is rapidly consumed upon maturation (paragraph [0126]). The expression level of these genes, therefore, changes as hematopoietic cells mature. A small increase in the rate of production of erythrocytes and platelets upon increased hematopoiesis may lead to large fold changes in RNA levels of these genes (Example 21). Thus, expression levels of these RNAs are strongly correlated with the rate of hematopoiesis and the distribution of hematopoietic cells along their maturation pathway.

Therefore, Moore et al fails to anticipate the presently claimed invention as it does not teach each and every limitation of claim 1. Thus Applicants respectfully request that the Examiner withdraw the rejection of claim 1 under 35 U.S.C. 102(e).

Claims 92-98 are objected to for being dependent on a rejected claim. In view of the above arguments, Applicants respectfully submit that the objections are now moot.


V. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 506612000104. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: July 1, 2008

Respectfully submitted,

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